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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,694	12/22/2003	Murty N. Arimilli	18477.031 / 259.PC2	1095

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WASHINGTON, DC 20004-1206

EXAMINER
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HUMPHREY, LOUISE WANG ZHIYING

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/740,694	<b>Applicant(s)</b> ARIMILLI ET AL.	
	<b>Examiner</b> Louise Humphrey, Ph.D.	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3,30-33,62-65,93-96 and 123-125 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,30-33,62-65,93-96 and 123-125 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Non-Final Office Action is in response to the After-Non-Final amendment filed on 21 June 2006. Claims 4-29, 34-61, 66-92, 97-122, and 126-180 have been cancelled. Claims 1-3, 30-33, 62-65, 93-96, and 123-125 are pending.

#### Objections

The objection to the specification is **withdrawn** in view of the Applicant's amendment correcting the typographical errors.

#### Claim Rejections - 35 USC § 112

Applicant's arguments with respect to the rejection of claims 30-33, 62-65, 93-95, and 123-125 under 35 U.S.C. §112, second paragraph, as being indefinite have been fully considered and are persuasive. Therefore, the rejection has been **withdrawn**. However, upon further consideration, a **new ground of rejection** is made in view of the lack of written description.

Claims 1-3, 30-33, 62-65, 93-96, and 123-125 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

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The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." M.P.E.P. §2163.

In the instant case, the claims are directed to a method for identifying a candidate compound as a suitable pro-drug using an extract of peripheral blood mononuclear cells (PBMC) having carboxylic ester hydrolase activity to convert a candidate compound into a metabolite compound or using GS-7340 Ester Hydrolase. The claims are drawn to

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genus of carboxylic ester hydrolases that are only defined by molecular weight range and the isoelectric point.

The only factor present in the specification is the physical and/or chemical properties: a molecular weight around 70-100 kDa, and a pI around pH 4.5-5.5 (p.1694-1698). The specification provides description for a single method of isolation, which yields an extract comprising ester hydrolysis activity. However, Applicants have not purified the enzyme to homogeneity and performed amino acid analysis to elucidate the structure of the instantly claimed products. There is no identification of any partial structure that correlates with the ester hydrolysis function.

As discussed above, the skilled artisan cannot envision the detailed chemical structure and function of the claimed GS-7340 Ester Hydrolase or the genus of carboxylic ester hydrolases. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of cloning or isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. A definition by function alone "does not suffice, to sufficiently describe a coding sequence" because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119F.3 at 1568, 43USPQ2d at 1406.

The genus of carboxylic ester hydrolases contains about 79 different enzymes ([www.brenda.uni-koeln.de/ectree/index.php4?ID=75&stype=7&PHPSESSID=c7af8a6f051020fcb37ac30a2aba5fc6](http://www.brenda.uni-koeln.de/ectree/index.php4?ID=75&stype=7&PHPSESSID=c7af8a6f051020fcb37ac30a2aba5fc6) ). The single method of isolation of PBMC extract does not reflect the variance in this genus because the specification does not identify

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the characterized vs. the uncharacterized and the known vs. the unknown carboxylic ester hydrolases in the claimed PBMC extract. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483, claims directed to mammalian FGF's were found to be unpatentable due to lack of written descriptions for that broad class. Accordingly, it is deemed that the specification fails to provide adequate written description for the claims and does not reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Therefore, claims 1-3, 30-33, 62-65, 93-96, and 123-125 do not meet the written description provision of 35 U.S.C. §112, first paragraph.

#### Claim Rejections - 35 USC § 102

Applicant asserted in the response filed on 21 June 2006 that the cited reference, Eisenberg *et al.* (2001) with issue numbers corresponding to April through July, is not published more than one year before April 26, 2002. However, Applicant has not provided data to support this assertion. Therefore, the rejection of claims 1-3 and 96 under 35 U.S.C. §102(b) as being anticipated by Eisenberg *et al.* (2001) is maintained until the Examiner receives confirmation on the electronic and paper publication dates from USPTO's Scientific and Technical Information Center.

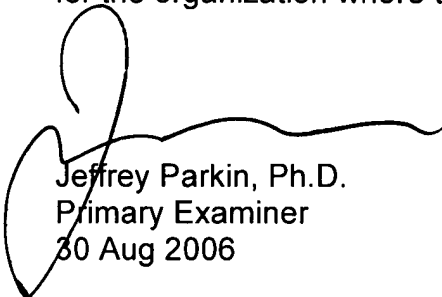
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**Contact Information**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Jeffrey Parkin, Ph.D.  
Primary Examiner  
30 Aug 2006

*LH*  
8/30/2006